REMARKS

Claims 1-4 and 7-31 are pending in the application. No claim amendments or cancellations are made in this Reply.

Sections 102 and 103(a) Rejections Overcome

Claims 1-4 and 7-33 have been rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a), as obvious over Mishelevich et al. (USP 5,363,842, 'Mishelevich').

Applicant respectfully traverses each and every aspect of this rejection.

Applicant's claimed invention relates to a hand-held dispenser for dispensing a multiplicity of unit products having a first dispenser part, comprising a storage area for storing the unit products, a second dispenser part, comprising a dispensing module mounted on the storage area, an outlet opening through which the unit products are dispensable from the dispenser, a dispensing mechanism actuable to dispense the unit products through the outlet opening, and a timing mechanism adapted in use to time the period since last dispensing of a unit product.

Applicant respectfully submits that Mishelevich does not anticipate independent claim 1 or the claims that depend therefrom as Mishelevich does not disclose all the features of independent claim 1. For example, Mishelevich does not disclose a storage area for storing unit products.

Mishelevic is related to a metered dose inhaler (MDI) where the "device detects how much air is inhaled through the inhaler with what time course (including such derived measurements as how much volume is inspired within the bounds of a given flow range) as well as certain events such as the triggering

of the release of aerosol." (see column 4, lines 35-40) As such, Mishelevic's device does not contain a first dispenser part, comprising a storage area for storing the unit products, but instead contains a reservoir of propellant and medicament, which is metered from the reservoir to form the dose. Mishelevic describes the discharge of the unit of medicine (column 9, lines 48-49) where the "Patient then places the mouthpiece **114** in mouth, depresses medication canister 102 flrmly enough to *cause metering mechanism **203** to discharge a unit of medicine through atomizer **242***, and the patient simultaneously begins to inhale." (emphasis added, see column 9, lines 46-50) Further, Mishelevic details how the dose provided to a patient by an MDI is very dependent upon the way the device is used by the patient (see, for example, column 2, lines 19-38). In sharp contrast, a dispenser which dispense preformed unit doses does is not susceptible to such an issue, and so the skilled person would not look to Mishelevic to provide a unit dose dispenser. Such an arrangement does not motivate, teach or suggest a storage area suitable for storing unit products.

Further, Mishelevic does not disclose a timing mechanism adapted in use to time the period since last dispensing of a unit product. The examiner has cited the following passage as reciting the specific element of claim 1:

> "The overall process of the present intelligent inhaler system is shown in FIG. 6A which provides an overview of the protocol for closing the therapeutic loop. The target profile envelope is selected and inserted (e.g., via a clinical computer-based workstation). This target envelope is (a) a generic pattern, or (b) a tailored time course based on the patient's individual spirometric values or other input, as appropriate. The device is used by the patient and at the next visit to the physician's office, the utilization data are extracted and trans-ferred to the clinical workstation where they are reviewed by the physician or other healthcare professional including analysis of trends with respect to previous periods. The prescription is adjusted ifand as appropriate and, if necessary, a new target proflle for the given patient and medication is loaded into the intelligent inhaler device.

> FIG. 6B is an overview of the process for utilization by the patient. Initially, the device reminds the patient that it is time to take the medication. This is used for 60 medications, such as corticosteroids, which are taken over long periods of time rather than in an immediate reaction to an acute event such as an asthmatic episode. The device is then turned on and the release of aerosol triggered." (see column 5, lines 41-65)

Mishelevic makes no mention of how this "reminder" is timed. The reference does describe that the device measures the duration of breath hold (see column 10, lines 11-14), starting when cessation of (inhaled) flow is detected. This corresponds to the cessation of inhalation and not to dispensation of the medication, which is recorded separately (column 9, lines 51-53).

> "Upon end of breath hold, *patient presses push button **104** which sends an event signal to microprocessor* in ASIC **220** for storage in RAM and *calculation of breath-holding duration*." (emphasis added, see column 10, lines 11-14)

Thus, it would appear that Mishelevic's timing corresponds to the cessation of inhalation and not to dispensation of the medication, which is recorded separately.

> "Depression of the canister **102** causes closure of actuation sensing switch 244 and transmission of a signal for this event to microprocessor within the control electronics of ASIC **220**." (see column 9, lines 50-53)

Clearly, the timing mechanism is triggered by an event which is different from to the last dispensing of a unit product as is claimed in the instant application. Mishelevic describes a device which monitors patient operation of a metered dose inhaler during dispensing but not at any other time, and which powers down after use (see column 10, lines 32-37). No detailed description of how the "reminder" feature operates is provided, hence it cannot be determined what exactly is decribed with regard to Fig 6B. In as far as Mishelevic considers

the dosing regimen used with the device, column 5, lines 4-11, ("In an alternate embodiment of the invention, the inhaler device would possess the capability to signal the patient at the times for which its use has been prescribed. This signal could be provided by means of indicator light(s), audible beeps or tones, vibration of the unit, or some combination thereof. Timing of such signals would be programmed in accordance with standard or patient-specific prescriptions for usage.") again the reference only mentions reminders according to fixed, prescribed times. Thus, contrary to the examiner's position on page 3 of the office action, the passage cited at column 5, lines 40-60 does not describe the "a timing mechanism adapted in use to time the period since last dispensing of a unit product." As such, there is no teaching, suggestion or motivation for a person of ordinary skill to adapt Mishelevic to measure elapsed time since the last dispensing of the device.

Applicant asserts that modification of either embodiment of Mishelevic to dispense unit products would fundamentally change its principle of operation. A person having ordinary skill in the art modifying the embodiment of Mishelevic for the dispensing of unit products would minimally have to provide a storage area for storing unit product (see figure 1, 100), a dispenser to dispense unit products (see figure 3, 305) and a modification of the circuitry to record time since dispensation in order to allow unit products to exit the device. Absent these features, this embodiment would be unable to record dispensation.

In view of the above, a withdrawal of the rejection over Mishelevic is respectfully requested.

Conclusion

All claim rejections being addressed in full, Applicant respectfully requests the withdrawal of the outstanding objections and rejections and the issuance of a Notice of Allowance. Should the Examiner have any questions regarding the foregoing, Applicant respectfully requests that the Examiner contact the undersigned, who can be reached at (919) 483-9995.

Respectfully submitted,

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Date: December 11, 2009
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